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No. 88-330

Supreme Court, U.S.
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IN THE

Supreme Court of the United States

OCTOBER TERM, 1988

AMERICAN CYANAMID COMPANY,
Petitioner,

v.

TRACY ISABEL ABBOT,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit

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BRIEF IN OPPOSITION

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BRIEF IN OPPOSITION

Respondent submits that this case does not warrant the Court's plenary consideration. The decision below is in accord with the uniform body of decisional law in the lower courts, and is plainly correct.

COUNTER-STATEMENT

The petition does not adequately describe the "design defect" claim that Respondent seeks to litigate. Respondent's claim is predicated on the following contentions which, in the present posture of this case (a motion for

summary judgment based solely on preemption), must be assumed to be true.

Respondent suffered severe and permanent neurological injuries that were caused by her innoculation, when she was five months old, with a whole-cell DTP vaccine manufactured and distributed by Petitioner. She seeks by this lawsuit to recover compensatory damages for her injuries.

Scientists have known for decades that whole-cell DTP is more dangerous than fractionated DTP.[1] It has also been known since at least 1963 that a fractionated DTP vaccine meeting FDA standards is achievable: in that year, Eli Lilly & Co. obtained FDA approval to market Tri-Solgen, a fractionated DTP vaccine.[2] During the mid-1960's, Petitioner developed its own fractionated DTP, which consistently passed the FDA prescribed tests for safety and efficacy. Petitioner believed its fractionated product safer than its whole-cell, and was confident it could secure FDA approval to market a fractionated vaccine just as Eli Lilly had. In 1967, however, Petitioner reduced its budget for new-product development, and chose not to spend the money for the clinical testing that is a prerequisite to securing FDA approval. Thereafter, throughout the period 1967-1981, Petitioner engaged in no research or development whatsoever respecting pertussis. Instead, Petitioner simply continued marketing the whole-cell vaccine that it knew to be more dangerous—the vaccine that caused Respondent's injuries.

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[1] In fractionated DTP, a substantial part of the endotoxin has been removed from the cell. Endoxtoxin is known to cause neurological injuries, and it can be removed from the cell without affecting the vaccine's efficacy: endotoxin is not the part of the cell that confers immunity against pertussis.

[2] The FDA determined as recently as December, 1985, that Tri-Solgen still meets its standards for marketing as a DTP vaccine, but Eli Lilly withdrew altogether from the biological business in 1976, and has not marketed Tri-Solgen since.

Respondent contends that these facts establish that Petitioner was negligent in failing to design a safer vaccine, and/or that Petitioner breached an implied warranty of merchantability (Virginia's equivalent of strict liability).[3]

ARGUMENT

The preemption ruling by the court below is applicable only to injuries resulting from vaccinations administered prior to October 1, 1988. Petitioner acknowledges (Pet. 13-16) that the degree of federal preemption to be applicable to vaccinations after that date has been specified by Congress in the National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. § 300aa (West Supp. 1988) (hereinafter "1986 Act").[4] The ruling below does not warrant this Court's attention for the following reasons.

1. *There is no conflict.* Two courts of appeals and fourteen district courts all have concluded that design defect claims against whole-cell DTP arising from vaccinations prior to October 1, 1988 are not preempted. (The decisions are cited at Pet. App. 61a-62a n.2).[5]

Petitioner notes that the Fifth Circuit in *Hurley v. Lederle Laboratories*, No. 87-2578 (5th Cir., Aug. 17, 1988), while rejecting preemption generally, left open the possibility that a narrower preemption claim might be assertable if a particular set of facts could be shown (Pet.

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[3] On precisely this evidence, the Ninth Circuit upheld a jury verdict finding Petitioner negligent under Idaho law for failing to follow-through on development of a safer, fractionated DTP. *Toner v. Lederle Laboratories, A Division of American Cyanamid*, 828 F.2d 510, 514 (9th Cir. 1987), *cert. denied*, 108 S. Ct. 1122 (1988).

[4] *See*, 42 U.S.C.A. § 300aa-22. As we explain *infra*, the 1986 Act would not preempt the types of claims advanced here even if brought with respect to a vaccination administered after October 1, 1988.

[5] The only district court decisions finding preemption were the two reversed by the court of appeals' decisions in *Abbot* and *Hurley*, and a third that was reversed on reconsideration by the district judge who rendered it. (*Id.* 62a.)

18-20, citing Pet. App. 70a n.4). The Fifth Circuit closed its discussion of that possibility as follows:

> *We do not decide this question* since we do not have the benefit of a district court's reasoning on it. We wish to make clear, however, that our holding against general preemption *does not necessarily exclude the possibility of such a specific preemption.* [Pet. App. 70a, n.4, emphasis added.]

The reservation of an issue to another day hardly creates a conflict. And, as we explain in the margin, the "possibility" kept alive in *Hurley* does not stand up upon examination.[6]

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[6] The preemption issue whose resolution the *Hurley* court left unresolved would be presented for decision if it were shown that "the FDA processed all necessary and available data" and nonetheless "approv[ed]" whole-cell DTP (Pet. App. 70a, n.4). But Congress focused expressly on the preemption issue in the 1986 Act, and did not make this a basis for preemption. The congressional determination forecloses judicial implication of such a basis for preemption. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 252-56 (1984); *Abbot*, Pet. App. 7a-8a. As the *Hurley* court itself observed elsewhere in its opinion (*id.* 65a):

> [W]e believe that any case for preemption is doomed by the [1986 Act] . . . . [That Act is] proof that Congress intends no preemption of the state law liability of vaccine manufacturers.

Moreover, no matter how complete the data available to the FDA, its approval of whole-cell DTP would not logically justify exonerating manufacturers from liability for failing to develop safer alternatives. FDA approval does not mean that a vaccine has been made as safe as possible. The FDA evaluates only the vaccines submitted to it for approval, not what "might have been". As the *Hurley* court recognized:

> [T]he FDA is a passive agency: it considers whether to approve vaccine designs only if and when manufacturers come forward with a proposal . . . . Thus, the absence of FDA-approved alternatives to whole-cell vaccine does not indicate FDA disapproval of any such alternative. [Pet. App. 64a.]

[Continued]

2. *The decision below is plainly correct.* Even had Congress not expressly addressed the preemption question in 1986, there would be a strong presumption against preempting compensatory recoveries under state tort law given that, prior to the 1986 Act, no federal compensatory remedy existed. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *Abbot*, Pet. App. 5a-6a. But Congress *did* address the preemption question in 1986, and as the court in *Hurley* recognized, any arguable case for preemption that might have existed in the absence of the 1986 Act is "doomed" by that Act's passage (Pet. App. 65a). *See also, Abbot*, Pet. App. 7a-8a.

The 1986 Act resolves the preemption question against Petitioner's contention for two distinct reasons. First, the 1986 Act expressly addresses the preemption question with respect to both pre-Act and post-Act vaccinations, and in the case of the former declares without qualifica-

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[6] [Continued]

By the same token, FDA approval of whole-cell DTP does not signify that the FDA has determined that safer alternatives could not have been developed.

Petitioner points to the preface of the *Hurley* dictum, in which the court opined that "it would seem likely" that a more limited preemption exists (Pet. 19, quoting Pet. App. 70a, n.4). Given the *Hurley* court's rejection, elsewhere in its opinion, of the premises upon which that limited preemption necessarily would have to rest, we suspect that this was a typographical error in the opinion, and that the court meant to say "it would seem unlikely." If the court intended "likely," the footnote is inexplicably at war with the text of *Hurley* quoted earlier in this footnote, and the text states the correct analytical principles that should control.

Finally, Petitioner suggests that in this case the record "is complete enough to support just such a narrow preemption ruling" (Pet. 19). But the record contains nothing to suggest that "the FDA processed all necessary and available data"; the "record" to which petitioner points is an *amicus* brief filed in the court of appeals which does not cite anything in the record. And that *amicus* brief is wholly silent as to the diligence of Petitioner in seeking to develop safer alternatives.

tion that "State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a).[7]

Second, even had the 1986 Act not expressly rejected preemption with respect to tort claims arising from pre-Act vaccinations, the legislative history attending the enactment of the 1986 Act manifests unmistakably Congress' understanding that, as things stood prior to the Act's passage, state tort law operated free of any federal preemption whatever.[8] Thus here, as in *Silkwood*, "the importance of the legislation" is not merely in its terms, but also "in the assumptions on which it was based," 464 U.S. at 254—*i.e.*, Congress' "assumption that in the absence of some subsequent legislative action, state tort law would apply," *id.* at 252, 256.

Petitioner urges that the limited preemption mandated by the 1986 Act for *post*-Act vaccinations should be ap-

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[7] Petitioner erroneously states that "[t]he 1986 Act . . . applies only to vaccinations occurring on or after October 1, 1988" (Pet. 13). To the contrary, although October 1, 1988 is the effective date of the Act, the Act regulates claims arising from vaccinations prior to that date as well as those after. The Act creates federal compensation schemes for both pre-Act and post-Act vaccinations, albeit recoveries thereunder are much smaller for pre-Act than post-Act vaccinations, § 300aa-15, and exhaustion of the federal scheme is a prerequisite to filing a tort suit only in the case of post-Act vaccinations, § 300aa-11, 21. The preemption provision states, without distinction between pre-Act and post-Act vaccinations, that "State law shall apply" to tort suits subject to enumerated exceptions, *id.* § 300aa-22(a), and the exceptions by their terms are applicable only to post-Act vaccinations, *id.* § 300aa-22(b), (c).

[8] *Abbot*, Pet. App. 7a-8a. A comprehensive compilation of the voluminous legislative history showing that Congress believed there was no preemption prior to the 1986 Act is found in Respondent's Brief below, at pp. 16-23. We have lodged a copy of that brief (which bears the title "Corrected Brief for Plaintiff-Appellant") with the Clerk of this Court.

plied by the courts to *pre*-Act vaccinations as well, and that the design defect claims in the instant case would be preempted under the 1986 Act standards (Pet. 13-16). This argument is wrong in both its premises.

First, Congress made an explicit decision to apply the 1986 Act's limited preemption only to *post*-Act violations. The Act declares that "State law shall apply" to tort claims for vaccine-related injuries "[e]xcept as provided in" certain subsections. Those subsections specify exceptions (*i.e.*, preemption in certain respects) only with respect to injury resulting from "the administration of a vaccine after the effective date of [the Act]" (§ 300aa-22(b), (c)). Congress made this distinction in treatment between pre-Act and post-Act vaccinations for policy reasons, as we explain in the margin.[9] To impose those same exceptions on *pre*-Act vaccinations by judicial fiat would be in defiance of both the terms of the statute and the policy considerations that prompted Congress to shape the statute as it did.

Second, the design defect claims in the instant action would not be preempted even if they *were* subject to the 1986 Act's exceptions. As Petitioner acknowledges (Pet. App. 15 n.50), and as the legislative history confirms, the exception Petitioner invokes (§ 300aa-22(b)(1)) was designed to assure that in all States the defense proposed in comment *k* to the Restatement (Second) of Torts, § 402A, would be available. That defense "precludes

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[9] Congress regarded limited preemption as justifiable only if, in return, Congress was substituting "the availability of a comprehensive and fair compensation system." H.R. Rep. No. 908, 99th Cong., 2d Sess. 25, 26 (1986). In the case of pre-Act vaccinations, the 1986 Act provides only minimal compensation (with a maximum of $30,000 for the following elements *combined*: lost earnings, pain and suffering, attorneys fees and costs). § 300aa-15(b). By contrast, the 1986 Act's scheme for *post*-Act vaccinations is far more generous (including, *e.g.*, uncapped lost earnings, pain and suffering capped at $250,000, and reasonable attorneys fees and costs without cap). § 300aa-15(a), (e).

strict liability in tort for highly beneficial products that are *unavoidably* unsafe even when properly manufactured" (Pet. 15 n.50 emphasis added). Comment *k* is applicable only to design defect claims predicated on strict liability, and does not restrict in any way design defect claims grounded in negligence. *Toner v. Lederle Laboratories*, 112 Idaho 328, 732 P.2d 297 (1987) (citing cases). Respondent is asserting such a negligence claim here. Moreover, even with respect to strict liability claims, the defense is available only for products that are "unavoidably" unsafe, and whether the dangers of Petitioner's DTP design were "unavoidable" is a question that is hotly disputed in this case. See, e.g., *Graham v. Wyeth Laboratories*, 666 F. Supp. 1483, 1496 (D. Kan. 1987); *Martinkovic v. Wyeth Laboratories*, 669 F. Supp. 212 (N.D. Ill. 1987).

3. *Boyle v. United Technologies Corp.*, 108 S. Ct. 2510 (1988), has nothing to do with this case. *Boyle* states a rule applicable to "civil liabilities arising out of the performance of federal procurement contracts", *id.* at 2514. But as petitioner concedes (Pet. 22), the instant case involves a private sale of vaccine, with no government contract involved at all.

Petitioner notes that in other instances it *does* sell DTP vaccine to the federal government. But even in the case of injuries resulting from vaccines purchased by the federal government *Boyle* would be inapplicable. To begin with, Congress, acting with knowledge that the federal government is a purchaser of vaccines and that DTP is the most dangerous,[10] announced in the 1986 Act the extent of preemption it wants, and did not mandate preemption as broad as *Boyle*. The *Boyle* Court was implying preemption in the absence of a more explicit Congressional directive. But preemption turns on "the intent of Congress", *California Federal Savings & Loan Assoc.*

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[10] H.R. Rep. No. 908, *supra* n.9, at 5-6.

v. Guerra, 107 S. Ct. 683, 689 (1987), and where, as here, Congress has expressly addressed the preemption question, its determination is dispositive. *Silkwood*, 464 U.S. at 252-56.

In limiting preemption as it did in the 1986 Act, Congress made a determination that the federal interest is better served by *not* insulating vaccine manufacturers from liability beyond the limits stated in the Act. Congress balanced the federal interests in vaccine availability and price (those considered in *Boyle*) against the federal interest in promoting safer vaccines, and concluded that the limited preemption dictated in the 1986 Act was appropriate to effectuate the availability/price interests, but that greater preemption would unduly undermine state tort law's role as stimulus to the development of safer products.

> [The balance struck is] intended to provide a stable vaccine market with care for the injured *and incentives for safety.* Weakening *either* safeguard might dislocate immunization programs by limiting the availability of vaccines *or by failing to encourage research and development of better vaccines.*[11]

Moreover, even had Congress not spoken, injuries resulting from DTP purchased by the federal government would not be governed by the rule in *Boyle*. The government does not prefer whole-cell to fractionated DTP; on the contrary, FDA regulations expressly state that the

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[11] H.R. Rep. No. 391, Omnibus Budget Reconciliation Act of 1987: Report of the House Committee on the Budget To Accompany H.R. 3545, 100th Cong., 1st Sess. (1987) at 691 (emphasis added) (text of Report of House Committee on Energy and Commerce reporting out bill that was enacted to fund the 1986 Act).

Petitioner repeatedly suggests that the absence of preemption will imperil the continued availability of DTP vaccine (Pet. 6, 12, 17, 22). That, of course, is precisely the claim that the drug manufacturers advanced to Congress when the 1986 Act was under consideration. Congress found the claim a sufficient justification only for the limited preemption that appears in that Act.

FDA will approve any DTP vaccine—whether fractionated or whole-cell—that meets specified safety and efficacy tests (21 C.F.R. §§ 601.4(a), 620.1), and vaccines of both kinds have been approved in the past (*supra*, p. 2) "There is no basis for finding a federal interest in a particular form of the pertussis vaccine." *Hurley*, Pet. App. 64a. This, then, is one of the situations described in *Boyle* in which "[n]o one suggests" there should be preemption, 108 S. Ct. at 2516-17.

The foregoing distinctions no doubt explain why the United States, although advocating preemption in *Boyle*, advised the court below that it took no position on the preemption issue presented here. (Pet. App. 38a).

CONCLUSION

For the reasons set forth above, the petition for writ of certiorari should be denied.

Respectfully submitted,

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